



The American Medical Student Association

The Undue Influence of Free Drug Samples

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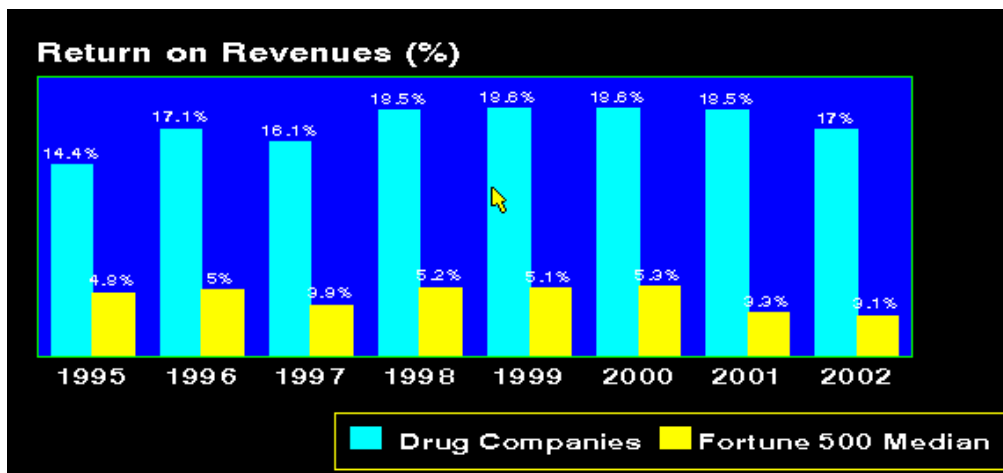


**Pharm
FREE** **LIBERATED**

Much research has gone into why it's poor practice for physicians to accept "gifts," and how this puts patients in secondary positions of priority. However, even the most upstanding and unbiased physicians find it difficult to turn down free samples of medication. There are many reasons why physicians could believe that this service is to their patients benefit. Free samples are a way for uninsured and underinsured patients to receive medication. Samples provide all patients, indigent or affluent, a way to test drugs for side effects and correct dosages before costly prescriptions are filled at the pharmacy. Free samples also allow for immediate treatment of symptoms between pharmacy trips, and allow doctors to see the effects of "new" and "innovative" drugs. So why speak out against such a valuable resource? This paper will discuss the impacts, implications, and influence free samples have on our profession.

"I'm overworked. I'm underpaid. I'm besieged on all sides by insurance companies. The only solace I get all day is a sales rep taking me to dinner and not complaining about anything."
 --John Doe, M.D.

Dr. Jerry Avorn, professor of medicine at Harvard Medical School has heard this sentiment all too often¹. What he and other physicians and health officials are learning is just how deep the roots of the doctor-industry relationship reach. The drug industry is a moneymaker the likes of which we haven't seen in the modern era before or since. The following data shows the profits of the pharmaceutical industry compared with the Fortune 500 average over seven years. Despite the risks associated with the introduction of new drugs into the market and the immense investment of resources required for research and trials, conglomerated pharmaceuticals have been far more profitable than any other industry. The data originates from Physicians for a National Health Program, reproduced from Fortune magazine.²



--phnp.org

How does this discrepancy occur? Drug companies are masters of marketing, both directly to the consumer, and more importantly to the physician. The pharmaceutical industry spent \$22 billion on marketing to physicians (including free samples) in 2003, up from \$12.1 billion in 1999, according to data from Pharmaceutical Research and Manufacturers of America (PhRMA). The industry was on track to spend almost \$3 billion in 2005 solely on meetings and events for physicians, according to Verispan, a health-care market-research firm in Pennsylvania.³

Aside from the billion-dollar advertising budget of any one pharmaceutical drug company, the conglomerates use connections at even the most trusted of government institutions to get products on the market. Marcia Angell, author of *The Truth About Drug Companies*, shares with us that the FDA now gets “user fees” from drug companies—about a half a million dollars for any drug that the FDA reviews. Those user fees are small for the companies, but it’s a substantial part of the FDA budget. In fact, it’s more than half [the budget for] the Center for Disease Evaluation and Research, which is responsible for approving new drugs. In return, the FDA is supposed to review drugs faster.⁴

Pushing drugs through the FDA translates to the familiar “ask your doctor” commercials directed toward consumers. These may have some effect on the dialogue between patient and physician; however, marketing initiatives directed to the doctor have much further reaching consequences because patients usually consider doctors as a primary source of credible information. Drug reps interact with physicians in numerous ways. Some reps offer doctors paid lunches over which they put forth a spiel about the drugs they sell. Others bankroll dubious symposia at which speakers are paid to speak in favor of certain drugs. Still other more subtle ways of marketing include product placement through pens, calendars, mousepads, gym bags, and even designer golf balls, all emblazoned with the company logo.

Hidden in the culture of medical practice, often unbeknownst to the physicians themselves are all the negative effects of free sampling. First, free samples are allocated under the “marketing and advertising” budget of the drug conglomerates, and for good reason. Evidence shows that advertising is an effective way to influence physician prescribing behavior. It is with this knowledge that drug companies allocate a disproportionate amount of resources to pharmaceutical rep. “detailing” visits in the hopes of getting their product prescribed.⁵ Samples limit patients’ knowledge of treatment options by focusing the discussion of available drugs to those that are most conveniently in the cabinet. Free samples, often while providing short term financial relief, turn into long term patient debt. The reason is simple; drug companies market the newest drugs that are inherently the most expensive. By accepting free samples, along with other paraphernalia, doctors are in a position where they are asked to reciprocate by prescribing drugs which are not first line, or not the physician’s first choice. Dr. Bob Goodman states that “Gifts are gifts. Whether they benefit patients or not, they're just freeing physicians' other income" in a way that creates indebtedness.”³ To the average person, drug companies do not appear to be as influential of a player in the realm of health care as some may project. This is certainly not the case. Pharmaceuticals influence everyone, from doctors to students to patients, all by way of advertising dollars.

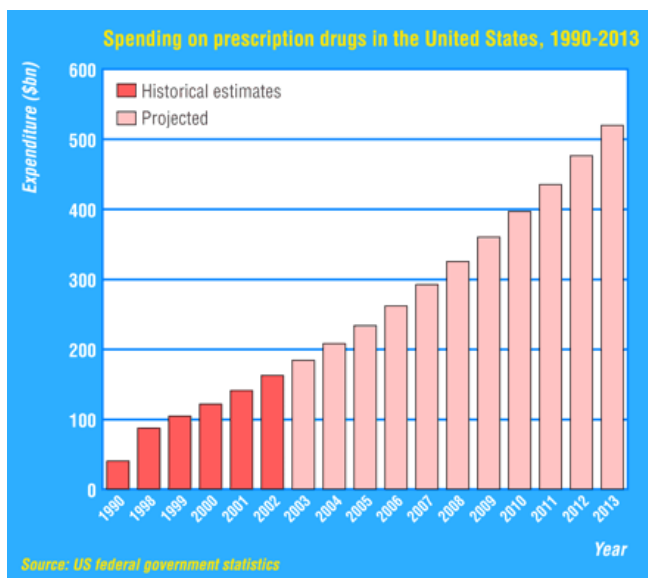
The pharmaceutical industry spent over \$12 billion in 1998 to promote its products in the United States. Of this promotional budget, over half was dedicated to supplying physicians with free sample medications for distribution to patients. This expense increased to almost \$15.7 billion in 2000, with free sample medications once more topping the budget, having increased an average of 12.8% annually since 1996. The extent of reaching physicians with this promotional strategy is remarkable, with one recent survey indicating that 92% of physicians had accepted free sample medications from pharmaceutical representatives.⁵

That may seem quite grandiose to most, but to localize the findings is to make it seem all the more startling. \$8000 to \$13,000 is spent per year on advertising to each physician.⁶

\$21 billion was spent by pharmaceutical companies on promotional endeavors in 1999. Approximately \$12 billion of this went toward free samples, constituting 56 percent of the promotional budget.⁷ “So what?” you may ask. CBO estimates that spending for outpatient prescription drugs for Medicare beneficiaries will total \$1.84 trillion over the 2004-2013 period.⁸ Free drugs may seem like a good option for those who are not covered by the Part D insurance plan. This astronomical figure only applies to Medicaid. The total annual spending by the rest of us with private insurance is increasing at an equally alarming rate. Spending in the US for prescription drugs was \$200.7 billion in 2005, almost 5 times more than the \$40.3 billion spent in 1990.²⁶

David Gross of the AARP public policy institute has some more figures to consider in a 2001 report: Between 2000 and 2010, prescription drug spending per American is expected to rise at an average annual rate of 11.2 percent. An estimated 20 percent of prescription drug spending increase is attributed to higher prices of newer drugs—those introduced since the mid-1990s—relative to older drugs that they are replacing.⁹

Source Data: U.S. Federal Government Statistics.⁷



Patients are always looking to save money on drugs, and may take free samples to do so. But the question still remains as to how physicians feel about free samples, and more generally, doctors’ interactions with pharmaceutical companies. It is indeed surprising how cozy the relationship is getting.

Physicians tend to be confident that they themselves are invulnerable to any bias inherent in the educational content offered or supported by drug companies. A study of residents found that 61 percent believed that they were not influenced by the marketing efforts of pharmaceutical companies

(although only 16 percent were equally confident about their colleagues). A majority of respondents tended to view a wide variety of interactions between drug companies and doctors as ethically acceptable. Examples included the receipt of pencils, pads, and expensive textbooks (valued at \$500 apiece), company-funded dinners at which the company's products were favorably mentioned, free drug samples for physicians' offices, free lunches for residents, and the presence of drug representatives during clinic hours and during company-supported "happy hours."¹⁰

It is true that medical students can see pharmaceutical reps as a ticket to nothing more than a free meal. However, physician confidence in their ability to withstand advertising is not shown in practice. Just take a look inside their coats.

A JAMA 2001 study of 164 primary care residents shows that not only did 98% eat a drug company-sponsored meal within the last year, but 97% had at least one item on their person at the time the survey was taken which bore a company logo. The leaders in this category were reference books, calipers, and pens.¹¹

More disturbing is the fact that some physicians are not aware of the ethical dilemma of the preceding scenario. One study⁹ found that 85% of medical students believe it is improper for politicians to accept a gift, whereas only 46% found it improper for themselves to accept a gift of similar value from a pharmaceutical company.⁶

44 percent of residents believe reps provide misleading information; 12-33% say that samples given by reps are inappropriate, while 55% say that samples influence their behavior. 33-60% of Physicians think that samples are inappropriate, with a similar percentage claiming influence. Another study quoted in the same paper showed that 86 percent of physicians think that samples should continue to be offered.⁶

As compared with physicians in hospitals or clinics and those in staff-model health maintenance organizations (HMOs), physicians in group practices were six times as likely to receive samples. 78 percent of physicians who responded to a questionnaire provided by researchers had received samples.¹²

In much the same vein, a news-target article by Jessica Fraser stated the following.

Researchers surveyed nearly 400 members of the American College of Obstetricians and Gynecologists about their relationships with pharmaceutical companies, and found that a third of respondents believed free drug samples influenced doctors' prescribing practices, though more than 90 percent thought accepting the samples was ethical

More than 50 percent of respondents to the survey believed that it was ethical to accept profitable consulting positions with drug companies for prescribing "high volume" amounts of that company's drugs.¹³

Nearly 85-90 percent of pharmaceutical advertising dollars is spent on doctors for free drug samples, speaker's fees, consultation fees, and "educational" grants.¹⁴ All this advertising has its adverse effects on patients in the form of rising costs and affecting physician prescribing behavior. A study by Chew et al, who surveyed 154 general medicine and family physicians at an academic medical center, showed interesting results. Nearly all physicians surveyed said that they would ideally choose a diuretic or β -blocker as initial therapy for hypertension. However, of the physicians who said they would use a sample for an uninsured patient with hypertension, more than 90% chose a sample that differed from their preferred choice.¹⁵

The study goes on to show more stirring statistics. When presented with an insured woman with an uncomplicated lower urinary tract infection, 17% of respondents reported that they would dispense a drug sample; 95% of sample users stated that they would dispense a drug sample that differed from their preferred drug choice. For an uninsured woman with depression, 82% of respondents reported that they would dispense a drug sample; 49% of sample users indicated that they would dispense a drug sample that differed from their preferred drug choice.¹⁵

Morelli and Koenigsberg inventoried drug samples in a family practice residency office and noted a high association between drug sample dispensing and simultaneous prescribing of the same brand-name drug, suggesting that sampling influences physicians' prescribing habits. This speculation was further studied and cited in the American Journal of Medicine. The study found that expensive drug prescription choice of residents increased from 36 percent to 43 percent with drug sample access. Advertised drugs were prescribed 35 percent of times up from 27 percent without sample excess. Sample access along with prescription availability changed habits from a frequency of 61 to 75%.¹⁶

Chren and Landefeld compared physicians who had requested additions to the hospital formulary (cases, n=40) with those who had made no such requests (controls, n=80). Physicians who had made requests were much more likely than the controls to have met with pharmaceutical representatives (odds ratio, 5.1; 95% confidence interval, 2.0-13.2). In addition, physicians who had interactions with specific companies were more likely to request drugs made by these, rather than unfamiliar, companies.¹⁷

Another wrinkle to the story is that when samples are prohibited, behaviors also change. Boltri and Gordon performed a controlled experiment in the Southeastern United States. A family medicine clinic was the focus, with 24 residents and 8 attending physicians. Data on prescription habits were collected in two distinct time periods. In January/February 1997, residents were allowed to give samples to patients. A policy change in August of that year led to a prohibition of samples. In January/February 1998, data was collected again. Prescription of first-line medication increased from 38% to 61% after sample distribution was prohibited. Similarly, in a study by Brewer that compared nonsteroidal antiinflammatory drug (NSAID) prescribing habits of physicians in three family practice residencies, the groups with limited drug samples had a higher rate of prescribing generic medications.¹⁸

It is clear that physicians are swayed by drug companies' ever-present advertisements, gifts, and free meals. Sampling leads to non-preferred prescriptions and treatment methods that are often at odds with physician preference and standard of care. However, the problem is compounded for patients in terms of cost and effectiveness of the medication. The Boltri study continues on:¹⁸

“Drug samples may encourage use of medications that are not first line, may be less efficient, and are often not compliant with standardized prescription guidelines. When prescribing drug samples, physicians are bypassing the pharmacy, thereby losing the protection provided by the pharmacy system that detects potential drug interactions with other medications. Indiscriminate use of the new antibiotics, encouraged by the use of samples, may intensify antimicrobial resistance.”

Doctors around the country are echoing this sentiment. Drug companies have a fiduciary responsibility to their stockholders and profit margins, not to patient welfare. “I’m really concerned that patients are being baited and hooked on free samples,” said Dr. Edward Langston, a physician in Lafayette, Ind., and a member of the American Medical Association Board of Trustees. “Sometimes there might be an economic incentive, but it might not be the right medical incentive.”¹⁹

Incentives or not, drug companies are cashing in. An example: AstraZeneca also offers consumers a seven-day free trial coupon for Nexium, a prescription brand chemically identical to its old heartburn drug, Prilosec, which is now sold over-the-counter. Although Nexium is more expensive than the over-the-counter version -- \$125.99 for 30 pills compared with \$19.99 for 28 pills -- AstraZeneca's marketing campaign for Nexium produced \$3.3 billion in sales in 2003.¹⁹ This adds up for individual patients. "IMS Health, a drug research firm in Plymouth Meeting, PA, found that drug companies handed out 766 million samples in 1999 or an average of 1,500 for each practicing physician. This amounted to several billions of dollars in free drugs across the nation."²⁰ If you measure free samples' success on the number of sold prescriptions, such tactics are second to none. "Schering Plough, for example, distributed 35.7 million samples of Claritin, an antihistamine that costs \$68 for a month's supply. The same amount of the generic antihistamine chlorpheniramine costs 62 cents."²⁰

Like most products, generic drugs' prices fluctuate in accordance with the number of competitors in the market. Approximately three-quarters of FDA-approved drugs have generic counterparts. Drug spending is also typically reduced when brand drugs lose patent protection and face competition from new, lower cost generic substitutes. According to an FDA analysis, on average for drugs sold from 1999 through 2004, the price of generic drugs fluctuates in direct correlation with the number of generic competitors in the market. For example, if a brand name drug has only one generic in the pharmacy, the generic drug will be sold for 94% of the brand name's price. With ten generics competing against each other and the brand drug, the price of each generic falls to 26% of the brand price. Further, with fifteen generics on the market, the price of each falls to thirteen percent of the brand name face value.²⁶ So, it is clear that encouraging the use of generics saves patient dollars in the long run by creating a market competition.

Physicians have a distinctly differing view of the effects of samples. Table 1, below, is from the Chew study, mentioned above. While most of the arguments in favor of samples come through in this survey (educational value, quick treatment), it is noteworthy that even physicians acknowledge that samples take away from valuable pharmacist interactions with patients that are vital in avoiding adverse drug reactions and possible replacement with less expensive generics. While most physicians in the study tended to hold the belief that samples permit treatment to start immediately, the same group of people believe that supplies of drug samples are inconsistent. Perhaps this has to do with the fact that drug companies switch which drugs they market to keep introducing newer more expensive names into clinics and into patient's homes.

Samples can also cause problems for physicians. Dr. Bruce Wolf of Vanderbilt described, in a letter to the editor of the *Journal of Allergy and Clinical Immunology*, the problem of excess quantities of samples in his cabinet. \$300,000 of sample medication was given to his practice in 1997, increasing to \$400,000 in 2004. Glaxo-SmithKline provided \$125,000 in Advair, which was spread out to three providers. Given the number of allergists in the U.S., conservative estimates place the value of all Advair given to allergists alone at over \$100,000,000.²¹

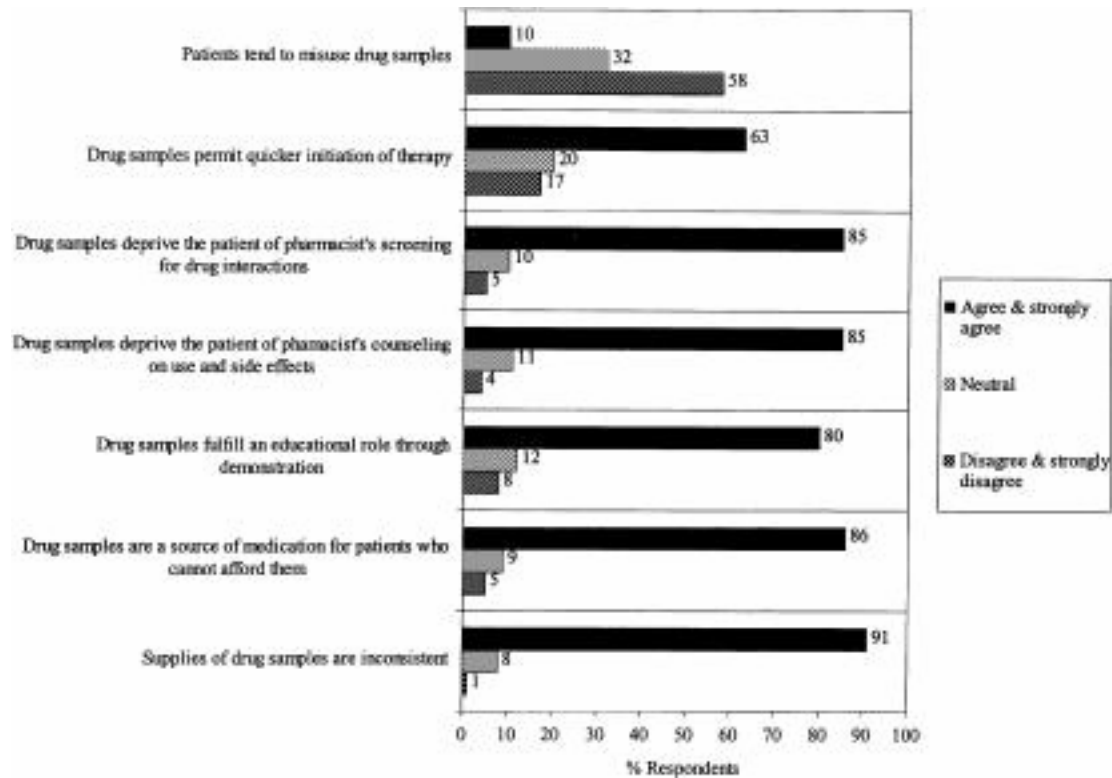


Table 1

Clearly the excess quantity of samples must be dealt with. Physicians often find themselves racing against the clock to distribute samples before they expire. Evidence shows that it is increasingly more common for samples to never reach patients. At times, samples are given to patients' family members who are not in the office. The Journal of Family Medicine published a study in 18 clinics of primary care. The study found the following:²²

Samples were used in 19.8% of the 1588 observed patient encounters. Multiple drugs were dispensed in 14.6% of the encounters in which samples were used. In only 5.1% of cases was a medication dispensed as a result of a patient's specific request; the clinician usually initiated the distribution of samples. Drug samples were also offered to additional family members in 3.5% of encounters, sometimes even when these individuals were not accompanying the patient to the given appointment.

Physicians and other employees of clinics often use samples personally. A study by Westfall and McCabe found that "only 54% of drug samples go to patients; the remainder is used by persons other than patients (i.e., physicians, family, and staff)."¹⁸ Tong and Lien's study revealed that of 27 pharmaceutical representatives surveyed; only 11 had not taken those sample medications themselves, provided them to friends or relatives, or exchanged them with other pharmaceutical representatives.⁵

In less than five years, the medication costs in the United States have doubled, rising from \$75 billion annually to over \$150 billion.⁵ Physicians often use free medical samples as a way to combat this problem. Researchers have found that this approach is harmful to patients as it influences physician decision making.

“The doctor will say, ‘Here, start on this, and let's see how it works,’” said David J. Rothman, president of the Institute on Medicine as a Profession, a research group at Columbia. “The question to the doctor is: If you didn't have it in your drawer, would that have been your drug of choice?”²³ These free samples de facto come at a price to patients, as heavily marketed and sampled drugs are the newest and most expensive drugs. Doctors and residents have an all-too-close relationship with drug reps at times, putting sponsored lunches and free textbooks in front of the needs of the people they serve. Dr. Jonathan Mohrer, an internist in Forest Hills, Queens, said he closed his sample cabinet in part because his office was overrun with sales representatives. “It was totally spinning out of control,” Dr. Mohrer said. “They were meeting each other and schmoozing in the waiting room - it was like a party.”²³

Moreover, drug companies distort facts about expenses and incomes. Sure, if you were to look at the annual report of a conglomerate like Pfizer, you'd see colorful splash pages featuring photographs of physicians in a laboratory. The text would be littered with words like “innovation,” “outreach,” and “breakthrough.” What we are to believe is that the industry invests hundreds of millions of dollars purely in research and development. Marcia Angell disputes this:⁴

The industry arrives at that \$802 million [per drug] figure by looking at a tiny handful of the most costly drugs. Those are drugs that were developed entirely in-house, and that are new molecular entities. That's a *very* tiny handful of the drugs that come to market each year. They're the most expensive drugs. Second, even for those drugs, they come up with a figure of \$403 million per highly selected drug. They then double that to \$802 million simply by adding in what they call the “opportunity costs” — what they could have made if they'd spent the same money on investments.

To most economists, the concept of opportunity costs are important. They are the costs associated with the benefits a company forgoes in not opting to take other possible alternatives when making business decisions. Therefore, the preceding inclusion of forgone investments may seem legitimate at first glance when figuring drug cost. An economist may contend that such investment opportunities lost are more along the lines of sunk cost. Therefore, \$800 million seems like an inflation.

Secondly, with all of that money, even the discounted value, one would think that the industry pumps out new powerhouse drugs yearly. This is simply not the case. Angell continues, “Around 75 percent of new drugs approved by the FDA are me-too drugs. The industry likes to portray itself as the engine of innovation, but in fact its major products are me-too drugs—minor variations of drugs already on the market. For example, we have six cholesterol-lowering statins on the market right now; we have five SSRI anti-depressants; we have nine ACE inhibitors to treat high blood pressure.”⁴

The ethical dilemmas of these situations involving prescriptions and drug reps run about in clinics nationwide. According to a study entitled “Of Principles and Pens” published in the American Journal of Medicine, nearly 100% of surveyed residents find promotions like pens, guidebooks, and conference lunches appropriate. More telling numbers are that 80% of this same sample find items like medical textbooks, social meet and greets, and dinner lectures acceptable. 70% of residents thought that sponsored CME is appropriate as well.⁷ Doctors wearing coats with branded pens and calipers in their pockets may find it difficult to be objective.

Empirical data from studies published in JAMA and Journal of American medicine shows that “80% of physicians and residents meet with PRs and accept samples regardless of training program policy.”²⁴ Agrawal et. al published a study in Academic medicine claiming that “At baseline, approximately two-thirds of respondents reported using samples at least once in the past month” before intervention, and that among the sample, “The attitudes toward the five types of marketing show that drug samples were viewed most favorably.”²⁵ Despite all of these statistics, and despite the seemingly inextricable relationship that physicians have forged with drug companies over the years, there are steps that we as physicians and students can make to make health care more objective and patient-driven. We must move forward in this direction in the interests of our patients’ health and in the interest of saving our profession’s reputation.

The research shows us that actions must be taken by physicians to maintain a level of trust with patients. Students have a responsibility to practice evidence-based medicine on sound medical principles, and not corporate advertising dollars. Here are some ways that students can become proactive in the fight against conglomerated pharmaceuticals:

- Pledge to be PharmFree: AMSA’s initiative to eliminate and/or control industry interaction has burgeoned into nationwide action as a result of their pharm-free report card. Already, Stanford and the University of Michigan have become pharm-free. They do not allow samples, representatives, advertisements, or drug paraphernalia into their University Hospital systems.
- Replace samples in clinical closet space with well-researched, dependable, and cheaper generics which saves patients’ money.
- If you absolutely must accept gratuities from industry, make sure to follow AMA guidelines to make sure that gifts benefit patients directly, and are of trivial value.
- Decline invitations to corporate sponsored CME events.
- Pack your own lunch when attending lectures with industry-sponsored catering.
- Use a voucher system whereby participating drug companies reimburse clinics and hospitals for use of medication. University of Wisconsin’s hospital system planned to save 1.2 million dollars instantly by use of this program.²⁰
- Use only unbiased sources of prescribing information like The Medical Letter or the Prescriber’s Letter

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